

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



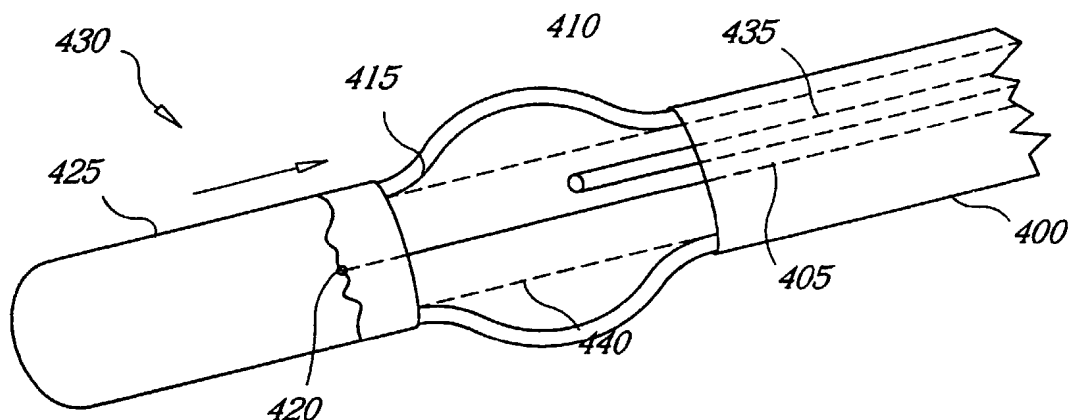
(43) International Publication Date
23 August 2001 (23.08.2001)

PCT

(10) International Publication Number
WO 01/60441 A1

- (51) International Patent Classification⁷: **A61M 25/10**, **A61B 18/02**
- (21) International Application Number: PCT/US01/02427
- (22) International Filing Date: 25 January 2001 (25.01.2001)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
09/491,239 25 January 2000 (25.01.2000) US
- (71) Applicants: **CRYOCATH TECHNOLOGIES, INC.** [CA/CA]; 16771 Chemin Ste-Marie, Kirkland, Québec H9H 5H3 (CA). **YOKLAVICH, Margaret** [US/US]; 335 N. 11th Street, San Jose, CA 95112 (US).
- (71) Applicants and
- (72) Inventors: **CARROLL, Sean** [US/CA]; 199 Hampshire, Beaconsfield, Québec H9W 3N8 (CA). **MARTIN, Robert** [US/US]; 50 S. Bridge Street, Poughkeepsie, NY 12601 (US).
- (72) Inventors: **WITTENBERGER, Dan**; 4806 Lucerne, Pierrefonds, Québec H8Y 2E2 (CA). **LÜCKGE, Claudia**; 4849 Legault Street, Pierrefonds, Québec H9J 3S5 (CA). **CAPUANO, Leonilda**; 5481 Queen Mary Road #34, Montreal, Québec H3X 1V4 (CA).
- (74) Agent: **CHRISTOPHER, John**; Gunster, Yoakley & Stewart, P.A., Suite 1400, 500 East Broward Blvd., Fort Lauderdale, FL 33394 (US).
- (81) Designated State (*national*): CA.
- (84) Designated States (*regional*): European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR).
- Published:**
- with international search report
 - before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: MECHANICAL SUPPORT FOR AN EXPANDABLE MEMBRANE



(57) Abstract: A medical implement that employs a mechanically supported expandable element. In one embodiment, the mechanically supported expandable element is a balloon. In another embodiment, the mechanically supported expandable membrane is a balloon disposed within a cryogenic catheter usable to treat tissue. A variety of illustrative mechanical support schemes are possible.



WO 01/60441 A1

MECHANICAL SUPPORT FOR AN EXPANDABLE MEMBRANE

FIELD OF THE INVENTION

The present invention relates generally to medical implements, and more particularly to a medical implement that employs a mechanically supported expandable membrane as part of the implement.

5

BACKGROUND OF THE INVENTION

It is well known to perform an angioplasty procedure to open an arterial vessel that, for example, is occluded due to arteriosclerosis. Typically, a balloon catheter is inserted into a patient's arterial network and manipulated to the occluded region of the vessel which is often proximate the heart. The balloon portion of the catheter is inflated so as to compress the arterial plaque against the vessel walls. The luminal area of the vessel is thereby increased, allowing more blood to flow through the vessel.

10

While the angioplasty procedure may initially be successful, a significant percentage of patients experience restenosis of the treated area. That is, the opened region of the vessel gradually recloses in a relatively short amount of time, such as about six months. Although the exact mechanism is not understood, restenosis is generally believed to involve platelet aggregation, thrombus formation, and smooth cell migration and proliferation, either singly or in combination. However it occurs, restenosis ultimately negates the benefits achieved by the angioplasty procedure.

15

In order to prevent mechanical recoil of the vessel wall following angioplasty, as well as to mitigate the effects of restenosis, a stent may be implanted in the opened region of the vessel after the angioplasty procedure. As known to one of ordinary skill in the art, a typical stent has a generally cylindrical shape to conform to the vessel and can be formed from a wire mesh. However, stents may irritate the vessel wall. Further, in some patients stents are believed to be the cause of rapid tissue growth, or intimal hyperplasia, through openings in the stent walls.

20

25

Some prior art devices and methods have called for the use of cooling treatment to prevent restenosis. For example, U.S. Patent No. 5,417,653 briefly discusses a method of inhibiting restenosis by reducing the temperature of tissue at a treatment site by infusion of a

fluid such as n-saline. However, fluid infusion as a treatment method may be inaccurate in targeting desired tissue and may introduce unwanted fluids or pathogens into a patient.

It would, therefore, be desirable to provide a device capable of treating a vessel region to prevent restenosis without the disadvantages highlighted above.

5

SUMMARY OF THE INVENTION

The present invention provides a medical implement comprising an expandable membrane with an element disposed within a lumen formed by the membrane. One embodiment of such an implement may be a mechanically supported balloon used as part of a catheter. In yet another embodiment, a mechanically supported balloon is incorporated as part of a cryogenic catheter that delivers cryogenic energy to minimize restenosis of a dilated region of a treated blood vessel. Cryogenic fluid is delivered to the expanded balloon and thereby cools the tissue in contact with an outer side of the balloon. Mechanical support for the balloon may, for example, be provided by a helical shape memory coil or a series of shape memory sections that deform against an inner side of the balloon, thus inflating the balloon. A variety of alternate mechanical support schemes may be employed to reach a similar result.

10

15

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be more fully understood from the following detailed description taken in conjunction with the accompanying drawings, in which:

20

FIG. 1 is a schematic diagram of a cryosurgical system including a catheter for use in conjunction with the present invention;

FIG. 2 is a side view of a tip region of the catheter of FIG. 1;

FIG. 3 is a side view of an alternative embodiment of the catheter tip region of the FIG. 2;

25

FIG. 4 is a side view of another embodiment of the catheter tip region of FIG. 1;

FIG. 5 is a side view of a further embodiment of the catheter tip region of FIG. 1;

FIG. 6 is a partial cutaway of a side view of yet another embodiment of the catheter of FIG. 1;

30

FIG. 7 is a pictorial diagram of a balloon catheter inflated within an artery;

FIG. 8 is a pictorial diagram of a stent being expanded by a balloon catheter;

FIG. 9 is a side view of a mechanically supported expandable membrane where the mechanical support element is a helical coil;

FIG. 10 is a side view of a mechanically supported expandable membrane where the mechanical support element is a plurality of radially spaced members;

5 FIG. 10A is a cross-sectional view taken along section A-A of the implement of FIG. 10, where the balloon is not expanded;

FIG. 10B is a cross-sectional view taken along section A-A of the implement of FIG. 10, where the balloon is expanded;

10 FIG. 11A is a pictorial diagram of another embodiment of a mechanically supported expandable balloon, shown with the balloon in an unexpanded state;

FIG. 11B is a pictorial diagram of the implement of FIG. 11A, shown in its expanded state;

FIG. 12A is a pictorial diagram of yet another possible embodiment of an expandable balloon with mechanical support, shown with the balloon in an unexpanded state;

15 FIG. 12B shows the implement of FIG. 12A in its expanded state;

FIG. 13A is a pictorial diagram of another illustrative embodiment of a mechanically supported expandable balloon, where the mechanical support is provided by an inner membrane spaced apart from the balloon;

20 FIG. 13B is a cross-sectional view of the implement of FIG. 13A shown in its expanded state;

FIG. 14 is a pictorial diagram of yet another embodiment of a mechanically supported expandable balloon, employing as part of its support element a sleeve assembly;

25 FIG. 15 is a pictorial diagram of a further embodiment of a mechanically supported expandable balloon, employing as part of its support element a push rod that actuates and causes the support element to deform towards the balloon.

FIG. 16A is pictorial diagram of another embodiment of a mechanically supported expandable balloon, where the mechanical support is provided by an expandable spring; and

FIG. 16B is a pictorial diagram of the implement of FIG. 16A shown in an expanded state.

DETAILED DESCRIPTION OF THE INVENTION

The present invention provides a mechanically supported expandable membrane. The membrane may be a balloon with an element disposed within its lumen. The element may include one or more of a number of support schemes, some of which are discussed in the
5 illustrative embodiments below.

A mechanically supported balloon may, for instance, be used as part of a cryogenic catheter used to treat a vessel with cryogenic energy to prevent restenosis or to selectively ablate tissue. In general, such a catheter is inserted into the patient's vascular network and manipulated to a treatment site. The catheter is then expanded and energized so as to cool the
10 contacted tissue at the treatment site to a predetermined temperature for a desired amount of time. It is understood that a variety of cryogenic catheter configurations can be used to apply cryogenic energy levels to the treatment site. If desired, such a medical implement may also employ other means of treating tissue, such as RF energy or other method of heating tissue, either in combination with cryotherapy or as a separate treatment mode.

Typically, an occluded region of the vessel is dilated by means of a percutaneous transluminal coronary angioplasty (PTCA) which includes the use of a balloon catheter. The catheter is inserted into the patient, in the groin area for example, and manipulated to the occluded region of the patient's artery. The balloon is then inflated so as to increase the luminal area of the vessel and thereby increase blood flow through the artery. A stent, which
15 is expandable by the balloon catheter, can be placed within the treated area to prevent mechanical recoil of the vessel wall.

In accordance with the present invention, an expandable balloon is provided wherein a mechanical support element is disposed in the lumen of the balloon. When the element is in a second state, i.e., expanded, the element contacts an inner side of the balloon and thus the
20 balloon expands. The expanded balloon provides a region that contacts an inner lumen of a biological vessel or cavity, thereby allowing for cryogenic or hyperthermal treatment in irregularly shaped areas of a patient. Further, the mechanical support afforded the balloon allows for balloon expansion when the pressure outside the balloon is greater than the pressure inside the balloon.

FIG. 1 is a schematic illustration of an exemplary cryosurgical system for use with the
25 device of the present invention. The system includes a supply of cryogenic or cooling

fluid 10 in communication with the proximal end 12 of a flexible catheter 14. A fluid controller 16 is interposed or in-line between the cryogenic fluid supply 10 and the catheter 14 for regulating the flow of cryogenic fluid into the catheter in response to a controller command. Controller commands can include programmed instructions, sensor
5 signals, and manual user input. For example, the fluid controller 16 can be programmed or configured to increase and decrease the pressure of the fluid by predetermined pressure increments over predetermined time intervals.

In another exemplary embodiment, the fluid controller 16 can be responsive to input from a foot pedal 18 to permit flow of the cryogenic fluid into the catheter 14. One or more
10 temperature sensors 20 in electrical communication with the controller 16 can be provided to regulate or terminate the flow of cryogenic fluid into the catheter 14 when a predetermined temperature at a selected point or points on or within the catheter is/are obtained. For example, a temperature sensor can be placed at a point proximate the distal end 22 of the catheter and other temperature sensors 20 can be placed at spaced intervals between the distal
15 end of the catheter and another point that is between the distal end and the proximal end.

The catheter 14 includes a flexible member 24 having a thermally-transmissive region 26 and a fluid path through the flexible member to the thermally-transmissive region. A fluid path is also provided from the thermally-transmissive region to a point external to the catheter, such as the proximal end 12. Exemplary fluid paths include one or more channels
20 defined by the flexible member 24, and/or by one or more additional flexible members that are internal to the first flexible member 24. Also, even though many materials and structures can be thermally conductive or thermally transmissive if chilled to a very low temperature and/or cold soaked, as used herein, a "thermally-transmissive region" is intended to broadly encompass any structure or region of the catheter 14 that readily conducts heat.

Furthermore, while the thermally-transmissive region 26 can include a single,
25 continuous, and uninterrupted surface or structure, it can also include multiple, discrete, thermally-transmissive structures that collectively define a thermally-transmissive region that is elongate or linear. Depending on the ability of the cryogenic system, or portions thereof, to handle given thermal loads, the ablation of an elongate tissue path can be performed in a
30 single or multiple cycle process without having to relocate the catheter one or more times or drag it across tissue.

In some embodiments, the thermally-transmissive region 26 of the catheter 14 is deformable. An exemplary deformation is from a linear configuration to an arcuate configuration and is accomplished using mechanical and/or electrical devices known to those skilled in the art. For example, a wall portion of the flexible member 24 can include a metal braid to make the catheter torqueable for overall catheter steering and placement. Additionally, a cord, wire or cable can be incorporated with, or inserted into, the catheter for deformation of the thermally transmissive region 26. Further, a balloon can be incorporated into the thermally transmissive region 26 such that the catheter can dilate the occluded region of the vessel as well as treat the dilated region with cryogenic energy.

In other embodiments, such as those shown in FIGS. 2, 3 and 4 for example, the catheter, or portions thereof, have two or more thermally-transmissive segments in a spaced-apart relationship. Each of the illustrated catheters includes a closed tip 32 that can include a thermally-transmissive material.

With respect to the embodiments shown in both FIGS. 2 and 3, the thermally-transmissive elements 34 are substantially rigid and are separated and/or joined by a flexible material 44. However, in other embodiments the thermally-transmissive elements 34 are flexible and are interdigitated with either rigid or flexible segments. FIG. 4, for example, illustrates an embodiment of the cryogenic catheter having three thermally-transmissive elements 34 that are flexible. The flexibility is provided by a folded or bellows-like structure 50. In addition to being shapable, a metal bellows can have enough stiffness to retain a selected shape after a deforming or bending step.

Instead of, or in addition to, flexible, thermally-transmissive elements 34 and/or flexible material 44 between elements, the distal tip 32 (or a portion thereof) can be deformable. For example, FIG. 5 illustrates a tip 32 having thermally-transmissive, flexible, bellows 50.

FIG. 6 illustrates another embodiment of a cryogenic cooling structure that includes a surface or wall 110 including a polymer or elastomer that is thin enough to permit thermal transfer. For example, polyamide, PET, or PTFE having a thickness of a typical angioplasty balloon or less (below 0.006 inches) provides acceptable thermal transfer. However, the thinness of the wall 110 allows it to readily collapse or otherwise deform under vacuum or near vacuum conditions applied to evacuate fluid/gas from the structure. Accordingly, the

structure is provided with one or more supporting elements 112 such as a spring. It should be noted that a variety of other supporting elements may be used to achieve the same goal and, as such, further support embodiments are discussed below. The cooling structure is illustrated in association with a catheter 114 having a closed distal tip 116 and mono or bipolar ECG rings 118, 120, 122. The thermally-transmissive region is approximately 30 mm in length and is effective for thermal transfer over its entire circumference. However, the thermally-transmissive region can be confined to specific region(s) of the device's circumference.

It is understood that other types of cryogenic catheters having differing types of distal tips can be used. Further exemplary catheters that can be used in conjunction with the method of the present invention are shown and described in co-pending and commonly assigned U.S. Patent Application No. 08/893,825, filed on July 11, 1997, incorporated herein by reference.

In an exemplary procedure, a cryogenic catheter having a ten millimeter cooling segment with a five French diameter, which can be obtained from CryoCath Technologies Inc. of St. Laurent, Quebec, Canada, is inserted into the patient's arterial network. The catheter is then manipulated to a region of the vessel that is dilated using a conventional PTCA, for example. A distal tip of the catheter is positioned so as to contact the dilated region of the vessel. The catheter is then energized so as to cool the tissue in contact with the distal tip of the catheter.

Cryogenic energy can be applied to the treatment site in a wide range of temperatures and for various time intervals depending on the desired effect. By varying treatment parameters, treated tissue may be ablated or left viable to a desired degree. For example, energy can be applied such that the tissue temperature is constant or it can vary. Further, energy can be applied for one or more predetermined time intervals at the same or different temperatures. The time intervals can vary as well, so as to achieve a desired level of cryogenic treatment for the target tissue. Also, certain areas of the treatment site may be cooled to a greater or lesser extent than surrounding target tissue.

In general, the tissue at the treatment site, e.g., the region of the vessel or vessel opening in need of dilation, is cooled to a temperature in the range from about zero degrees Celsius to about minus one hundred and twenty degrees Celsius for a period of time ranging

from about ten seconds to about sixty minutes. It is understood that as tissue is cooled to more extreme temperatures the duration of the treatment can be decreased. In one embodiment, the treatment site is cooled to a temperature of about minus fifty degrees Celsius for about two minutes. Of course, if tissue ablation is the desired result, the treatment temperature may be further depressed and/or the duration of the treatment may be increased beyond the treatment parameters disclosed above.

In contrast with heat and radiation tissue treatments, the application of cryogenic energy produces less damage to the arterial wall structure. The damage reduction occurs because a freeze injury does not significantly alter the collagen structure as compared with the application of heat. Further, a freeze injury does not significantly reduce the reproductive/repair capability of the living tissue as compared with radiation treatments.

As shown in FIG. 7, cryogenic energy can be applied to a vessel region 124 dilated with a balloon catheter 126, wherein the balloon catheter is infused with a cryogenic fluid and maintained in contact with tissue for a period of time as described above. Although this procedure can have a restenosis effect, a surgeon may also wish to implant a stent. Thus, in another exemplary procedure, a balloon dilated region of a vessel is treated with cryogenic energy prior to implantation of a vascular stent. By treating the tissue with cryogenic energy, rapid tissue growth or so-called remodeling commonly associated with implanted stents is believed to be reduced or substantially prevented.

As shown in FIG. 8, a stent 128 can be expanded by a cryoballoon catheter following the cryo-treatment of a vessel 132 or simultaneous with the cryo-treatment. Also, the stent can be expanded and then cryo-treatment can begin.

Referring now to FIG. 9, a balloon catheter 200 has a proximal segment 230 distal to a proximal end (not shown). The proximal segment 230 has running through it a conduit 225 for delivering cryogenic fluid to a distal side of the proximal segment 230. The proximal segment 230 also has therein a pull wire 219 that terminates at a connection point 217, thereby fixedly attaching the pull wire 219 to a helical coil 220 (discussed below). The proximal segment 230 is adjacent to a balloon region 210 and is sealed at its distal end to the balloon membrane 230. The distal side of the balloon membrane 230 is sealed on its distal side to the distal segment 205. The seals between the balloon membrane 230 and the distal end of the proximal segment 230, and between the balloon membrane 230 and the proximal

end of the distal segment 205, prevent both the entry or exit of fluids into or from the catheter 200.

It should be noted that the balloon membrane 215 is shown in an expanded condition. Contacting an inner wall 235 of the balloon membrane 215 is a helical coil 220. The helical coil 220 is shown in a second state, i.e., expanded, such that the diameter of at least a portion of the helical coil 220 is greater than the diameter of the same portion when the helical coil 220 is in a first state, i.e., relaxed. The expansion of the helical coil 220 may, for example, be effectuated by a simple actuation at the proximal end (not shown) of the balloon catheter 200, i.e., a lever or switch connected to the pull wire 219, or by constructing the helical coil 220 of shape-memory material, or a combination thereof. A change in temperature may also be used to expand the helical coil 220.

In operation, cryogenic fluid from the conduit 225 enters balloon membrane 215 when balloon membrane 215 is in the expanded condition. The cryogenic fluid expands upon entering the balloon membrane 215, thereby creating a cooling effect. Tissue in contact with the balloon membrane 215 is cooled to the desired temperature. Other methods of cooling using a fluid flowing through a balloon membrane such as balloon membrane 215 are readily evident, such as sustaining a fluid flow rate through the balloon membrane 215 sufficient to achieve the desired cooling of tissue in contact with the balloon membrane 215.

Another embodiment that demonstrates the use of a mechanically supported expandable membrane is seen in FIG. 10. As discussed in relation to FIG. 9, a balloon catheter 300 has a proximal segment 330 leading to a proximal end (not shown) and a distal segment 305. The proximal segment 330 has running through it a conduit 325 for delivering cryogenic fluid to a distal end of the proximal segment 330. The balloon region 310 includes a balloon membrane 315 sealed to the distal segment 305 and sealed to the proximal segment 330 so as to prevent the both the entry or exit of fluids into or from the catheter 300. The balloon membrane 315 is shown in an expanded condition.

Contacting an inner wall 335 of the balloon membrane 315 is a plurality of radially spaced apart members 320. The plurality of members 320 converge proximally at junction 335 and distally at junction 340. Changing the distance between junction 335 and junction 340 allows for selectable transitionability between a first state and a second state. In FIG. 10, the plurality of members 320 is shown in a second state, i.e., expanded, such that the diameter

of at least a portion of the plurality of members 320 is greater than the diameter of the same portion when the plurality of members 320 is in a first state, i.e., relaxed.

FIGS. 10A and 10B illustrate the differences between the first state and the second state. In FIG. 10A, the balloon membrane 315 is unexpanded and the plurality of members 320 is in the first state. Comparing FIG. 10A to FIG. 10B, in FIG. 10B the balloon element 315 has expanded, as is dictated by the configuration of the plurality of members 320 in the second state. It should be noted that in this expanded condition, cryogenic fluid is able to flow from the conduit 325 into the lumen of the balloon member 315, thus effecting cooling of tissue contacting the balloon member 315.

In FIGS. 11A and 11B, the element within the lumen of the expandable membrane is deformable wire mesh that is expanded when either a proximal segment of a catheter is moved towards a distal segment, or when a distal segment is moved towards a proximal segment. The expanded mesh region defines a cooling region should cryogenic fluid be circulated through the catheter.

Referring to FIG. 11A, a proximal segment 400 has running through it a pull wire 405 and a fluid conduit 435. The pull wire 405 exits the proximal segment 400 at a distal end and continues through the mesh region 410 and terminates within the distal segment 425 at a connection point 420. The connection point 420 may be attached to the distal segment 425 such that when the connection point 420 moves either proximally or distally, the distal segment 425 moves with it. The mesh region 410 has on its inner side, i.e., within its lumen, medial segment 440, within which fluid conduit 435 terminates. An outer side of the mesh region 410, is surrounded by the balloon membrane 415, balloon membrane 415 being sealed at a proximal end to the proximal segment 400 and at a distal end to the distal segment 425 such that fluids are incapable of exiting or entering the catheter 430.

FIG. 11B shows the catheter 430 of FIG. 11A with the balloon membrane 415 in an expanded state. Such a state is brought about by reducing the distance between the connection point 420 and the proximal segment 400. The reduction in distance, for example, may be caused by actuating a lever or switch located at a proximal handle (not shown) of the catheter 430 such that a pull wire 405 is drawn towards the proximal handle. When the connection point 430 moves towards the proximal handle, the mesh region 410 deforms outwardly, thus achieving the desired expansion of the balloon membrane 415. As mentioned

above, one could achieve a substantially similar result by moving the proximal segment 400 towards the connection point 430. When the catheter 430 is in this expanded state, cooling fluid preferentially flows through fluid conduit 435 into the lumen of mesh region 410, thereby allowing cryogenic treatment to occur.

5 FIG. 12A demonstrates yet another embodiment of a mechanically supported expandable balloon. In this embodiment, a proximal segment 500 has running through it a pull wire 505. The pull wire 505 exits the proximal segment 500 at a distal end, continues through strut region 510, enters a proximal end of the distal segment 525, and terminates at a connection point 530. The connection point 530 may be attached to the distal segment 525
10 such that when the connection point 530 moves either proximally or distally, the distal segment 525 moves with it. The strut region 510 is surrounded by the balloon membrane 515, balloon membrane 515 being sealed at a proximal end to the proximal segment 500 and at a distal end to the distal segment 525 such that fluids are incapable of exiting or entering the catheter 535.

15 FIG. 12B shows the catheter 535 of FIG. 12A with the balloon membrane 515 in an expanded state. Such a state is brought about by reducing the distance between the connection point 530 and the proximal segment 500. Once again, the reduction in distance, for example, may be caused by actuating a lever or switch located at a proximal handle (not shown) of the catheter 535 such that a pull wire 505 is drawn towards the proximal handle.
20 When the connection point 530 moves toward the proximal handle, the strut region 510 deforms outwardly, thus achieving the desired expansion of the balloon membrane 515. Alternatively, the proximal segment 500 could be moved towards the connection point 530 to achieve a substantially similar result.

25 FIG. 13 illustrates another embodiment having a second expandable membrane, such as a balloon, disposed in the lumen of the first expandable membrane. The inner balloon is spaced apart from the expandable membrane by a series of radially spaced members. Thus, when the inner balloon element is expanded, the spacers are forced against the inner wall of the expandable membrane, thereby causing expansion of the membrane.

30 Specifically, FIG. 13 shows a catheter whose proximal segment 600 preferably includes within it an air supply line 605 and a fluid supply line 620. The air supply line 605 terminates in an inner balloon 610, shown in an expanded condition. It should be noted that

air inflation of the inner balloon 610 is merely one of a number of possible expansion methods. The inner balloon 610 has surrounding it a plurality of members 630, spaced radially apart around a longitudinal axis of the inner balloon 610. In this expanded condition, the members 630 contact an inner side 617 of an outer balloon 615. Cryogenic fluid may preferably be introduced into the space 618 created in this arrangement between the inner balloon 610 and the outer balloon 615 through fluid supply line 620.

Turning to another illustrative embodiment, in FIG. 14 a catheter 750 includes a sleeve 705 slidably engaged with a proximal segment 700. Running through the proximal segment 700 is a fluid supply line 720 and a pull wire 717. Pull wire 717 terminates at a connection point 719 on a slotted tube 718. The slotted tube 718 is shown being attached to a pair of deformable struts 730 at its proximal end. Further, a balloon membrane 715 is sealed at its proximal end to the proximal segment 700 and sealed at its distal end to a distal segment 725 such that fluids are incapable of entering the catheter 750. The balloon membrane 725 is shown in an expanded condition and is mechanically supported by deformable struts 730. In operation, the catheter 750 is guided to a desired treatment location within a patient's body. Once reached, a sleeve 705 is slid proximally, exposing the balloon membrane 715 to the treatment site. The struts 730 are then deformed outwards by pulling the pull wire 717 toward the proximal end of the catheter (not shown) such that slotted tube 718 moves in a proximal direction. Cryogenic fluid then enters the lumen of the balloon membrane 715, such that the desired treatment may be effectuated.

Referring now to FIG. 15, a catheter has a proximal segment 800 within which is disposed a push rod 817. A fluid conduit 835 is disposed within the push rod 817. Push rod 817 terminates at a point distal to the proximal segment 800 and separates into at least two flat metal wires 810. The flat metal wires 810 contact an inner surface of a balloon membrane 815 when the balloon membrane 815 is in an expanded condition, as is shown in FIG. 15. The flat metal wires 810 terminate at a proximal end of a distal segment 825 and are biased against the distal segment 825 such that when the push rod 817 is actuated in a distal direction, i.e., a force F is applied in the direction shown in FIG. 15, the flat metal wires 810 deform against the inner surface of the balloon membrane 815, thereby expanding the balloon membrane 815.

Referring now to the catheter tip embodiment illustrated in FIGS. 16A and 16B, a proximal segment 900 has running through it a guide wire system 905 and a fluid conduit 935. The proximal segment 900 is separated from a distal segment 925 by a gap of longitudinal distance D. The guide wire system 905 exits the proximal segment 900, traverses the gap, and terminates in an end of distal segment 925 at connection point 920. Disposed within the gap between proximal segment 900 and distal segment 925 is an expandable spring 910. The expandable spring 910 is connected to the proximal segment 900 at one end and to the distal segment 925 at the other end. The expandable spring 910 has surrounding it an expandable membrane 915.

In operation, a control at a proximal end of the catheter (not shown) imparts a rotation to the distal segment 925 by applying a torque to the guide wire system 905. Thus, as the guide wire system 905 is affixed to distal segment 925 at the connection point 920, when the guide wire system 905 is rotated, so is the distal segment 925. Similarly, as the distal segment 925 is affixed to the expandable spring 910, when the distal segment 925 is rotated, so is the expandable spring 910.

Throughout this procedure, the distance D between the proximal segment 900 and the distal segment 925 remains substantially constant; thus the rotation imparted to the expandable spring 910 serves to increase the profile of the expandable spring 910 in an axial direction instead of in a longitudinal direction. Alternatively, the same result may be achieved by imparting a rotation to the proximal segment 900 or by rotating the expandable spring 910 directly. When the expandable spring 910 is thus expanded, the expandable membrane 915 in contact with the expandable spring 910 is also expanded, thereby allowing for treatment of tissue contacted by expandable membrane 915. As discussed above, cryogenic treatment may be performed, for example, by the expansion of cooling fluid introduced into the lumen of the expandable membrane 915 through the fluid conduit 935.

It should be emphasized that any of the above suggested embodiments may employ as the method of deforming the element shape-memory alloys, changes in element length and/or diameter via physical actuation, temperature changes, or a combination thereof, to accomplish the invention. Further, it should be noted that additional features may be incorporated into the mechanically supported membrane of the invention, such as a deflection mechanism employing one or more pull-wires to enable steering of the catheter, or a plurality of ECG

electrode rings spaced longitudinally apart along the catheter to allow for monitoring activity proximate a treatment site. Other types of electrodes may also be incorporated, such as electrodes designed to deliver thermal energy for treatment or ablation. Finally sensors for measuring temperature and other physiologically relevant parameters may be provided as part of the invention.

One skilled in the art will appreciate further features and advantages of the invention based on the above-described embodiments. Accordingly, the invention is not to be limited by what has been particularly shown and described, except as indicated by the appended claims. All publications and references cited herein are expressly incorporated herein by reference in their entirety.

What is claimed is:

- 1 1. A medical implement, comprising:
2 an expandable membrane transitionable between a contracted state and an expanded
3 state, the expandable membrane having:
4 an outer side and an opposite inner side defining a lumen; and
5 a thermally transmissive region transferring thermal energy between the outer
6 side and the opposite inner side; and
7 a non-inflatable element disposed within the lumen, the non-inflatable element
8 supporting the expandable membrane, the non-inflatable element being operable to increase
9 the diameter of at least a portion of the non-inflatable element to support the expandable
10 membrane in the expanded state.
- 1 2. The medical implement of claim 1, wherein the non-inflatable element is comprised
2 of a deformable mesh.
- 1 3. The medical implement of claim 1, further comprising a catheter body joined to the
2 expandable membrane and having a proximal segment and a distal segment.
- 1 4. The medical implement of claim 3, wherein the expandable membrane is located at a
2 point between the proximal segment and the distal segment of the catheter body.
- 3 5. The medical implement of claim 4, wherein the distal end of the catheter body is
4 closed.
- 1 6. The medical implement of claim 3, further comprising at least one electrode in contact
2 with the catheter body.

1 7. The medical implement of claim 3, further comprising a fluid supply in fluid
2 communication with the lumen defined by the expandable membrane.

1 8. The medical implement of claim 7, wherein the fluid supply element is disposed
2 within the catheter body.

1 9. The medical implement of claim 7, further comprising a control console in fluid
2 communication with the fluid supply element, the console including a supply of cryogenic
3 fluid.

1 10. The medical implement of claim 9, wherein the control console further includes a
2 control means for controlling the operation of the non-inflatable element.

1 11. The medical implement of claim 3, further comprising, a sleeve
2 slidably engaging the catheter body, the sleeve substantially covering the expandable
3 membrane when the non-inflatable element has not been operated to increase the diameter of
4 at least a portion of the non-inflatable element.

1 12. The medical implement of claim 4, further comprising, a connection point disposed on
2 the distal segment of the catheter body, the connection point being selectively movable
3 between a first position and a second position, the distance between the connection point and
4 the proximal segment of the catheter body when the connection point is moved towards the
5 second position being less than the distance between the connection point and the proximal
6 segment of the catheter body when the connection point is in the first position.

1 13. The medical implement of claim 12, wherein the diameter of at least a portion of the
2 element increases as the connection point moves towards the second position.

1 14. The medical implement of claim 12, wherein the non-inflatable element is comprised
2 of a deformable mesh, and wherein the diameter of at least a portion of the deformable mesh
3 increases as the connection point moves towards the second position.

1 15. The medical implement of claim 12, further comprising a pull wire coupled to the
2 connection point, the pull wire extending through the lumen and the proximal segment of the
3 catheter body.

1 16. The medical implement of claim 15, further comprising a handle coupled to the
2 proximal segment of the catheter body, the handle having an actuating member coupled to the
3 pull wire, the actuating member being operable to cause the connection point to move
4 between the first position and the second position.

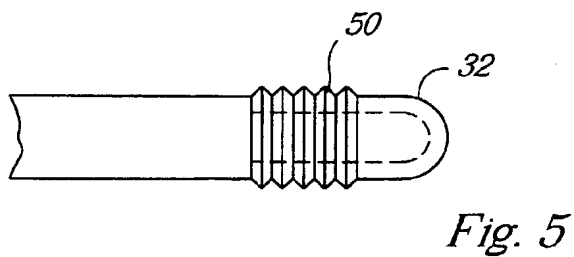
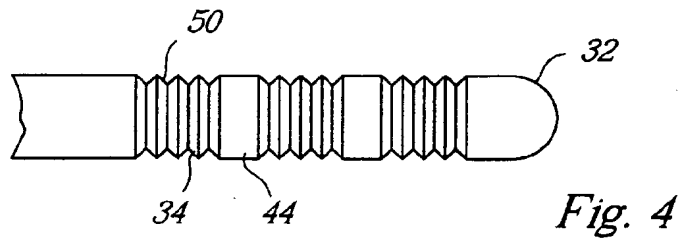
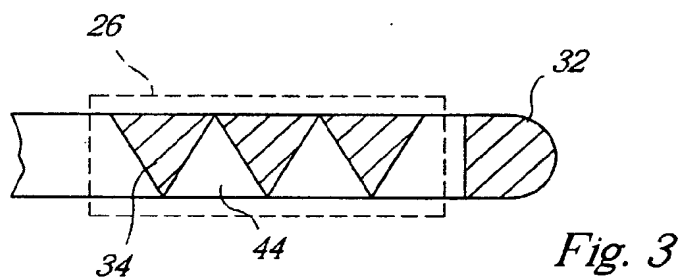
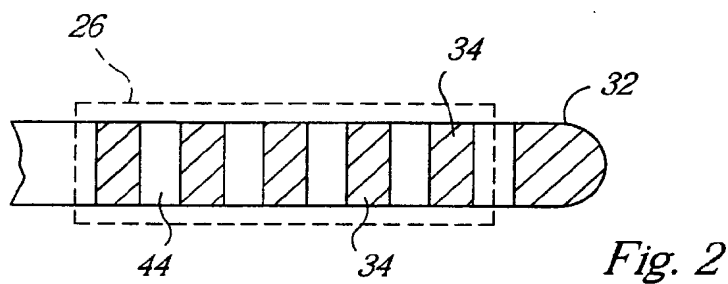
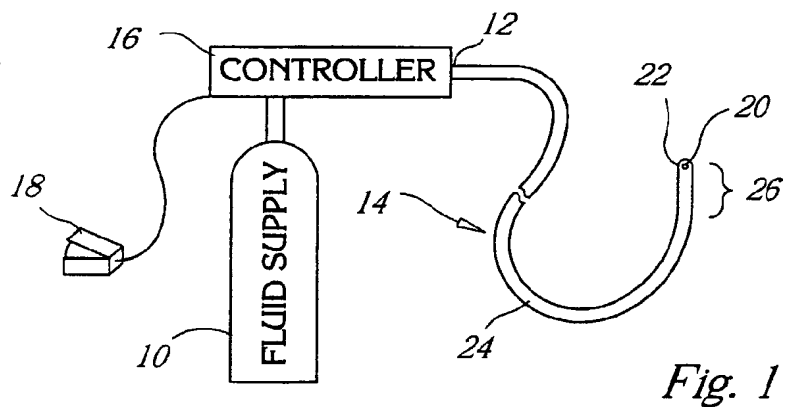
1 17. The medical implement of claim 3, further comprising a connection point disposed
2 proximally of the element, wherein the connection point is selectively movable between a
3 first position and a second position, the distance between the connection point and the distal
4 segment of the catheter body when the connection point is moved towards the second position
5 being less than the distance between the connection point and the distal segment of the
6 catheter body when the connection point is in the first position.

1 18. The medical implement of claim 17, wherein the diameter of at least a portion of the
2 element increases as the connection point moves toward the second position.

1 19. The medical implement of claim 1, wherein the non-inflatable member is operable to
2 cause the expandable membrane to remain expanded when a first pressure within the
3 thermally transmissive region is less than a second pressure on the outer side of the
4 expandable member.

1 20. The medical implement of claim 9, wherein the controller is operable to infuse the
2 cryogenic fluid into the thermally transmissive region and to apply a first pressure to evacuate
3 the cryogenic fluid from the thermally transmissive region, the first pressure being less than a
4 second pressure on the outer side of the expandable member, the non-inflatable member
5 being arranged to cause the expandable membrane to remain expanded during operation.

1/6



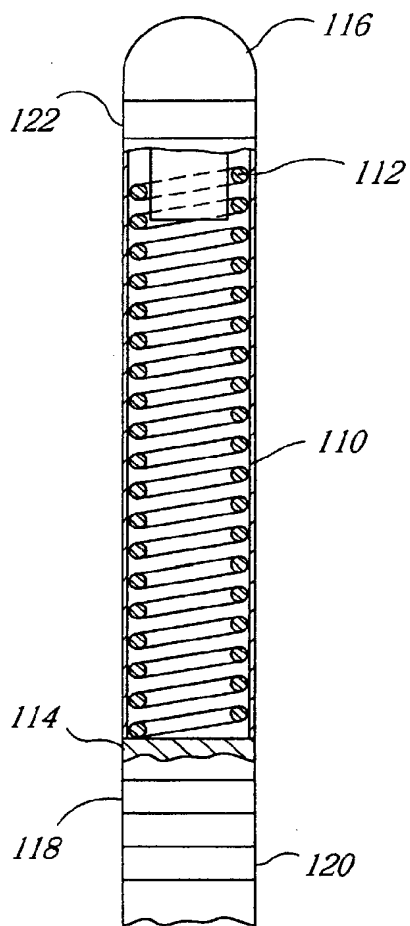


Fig. 6

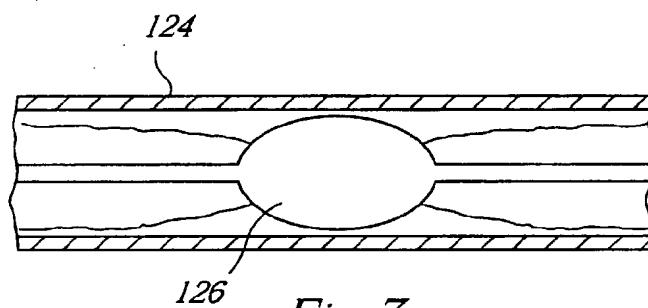


Fig. 7

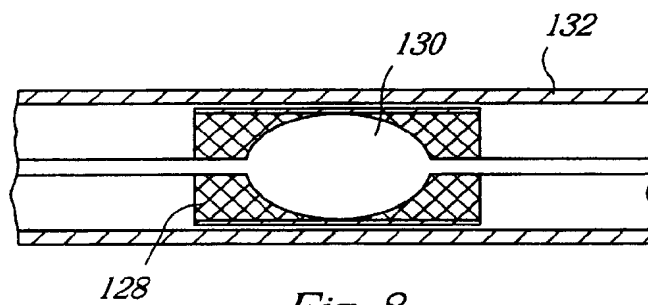
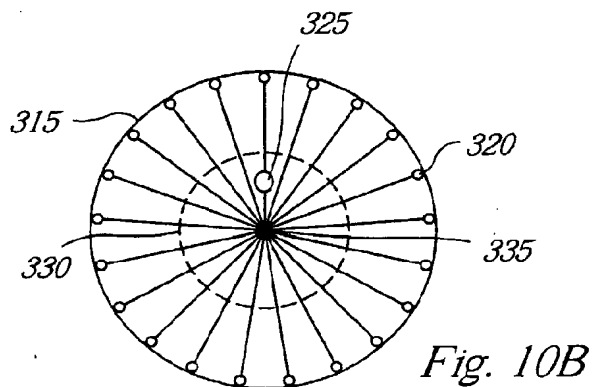
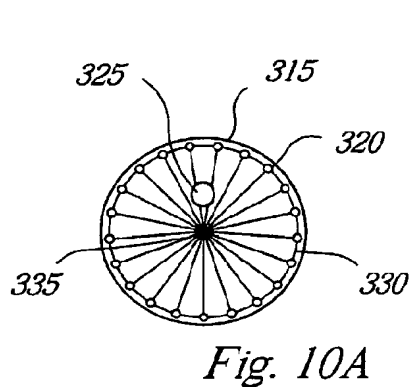
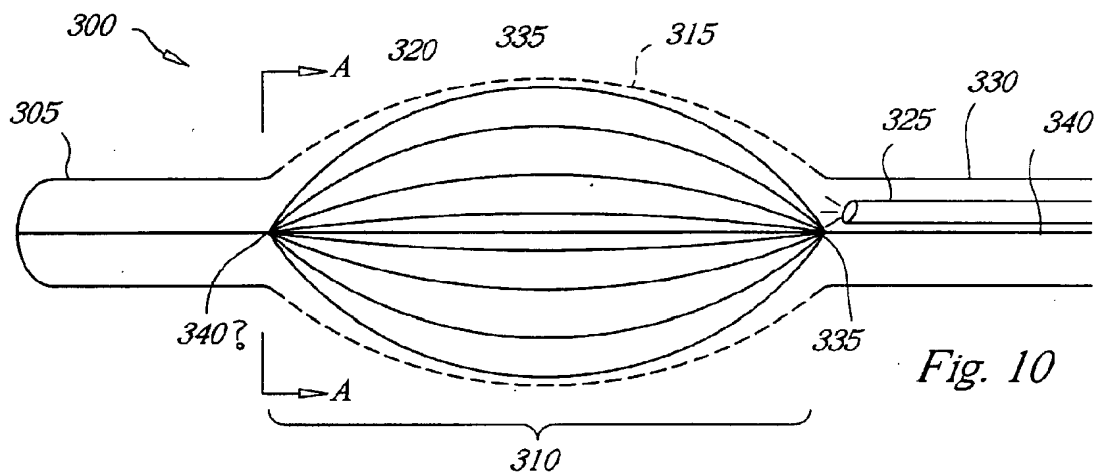
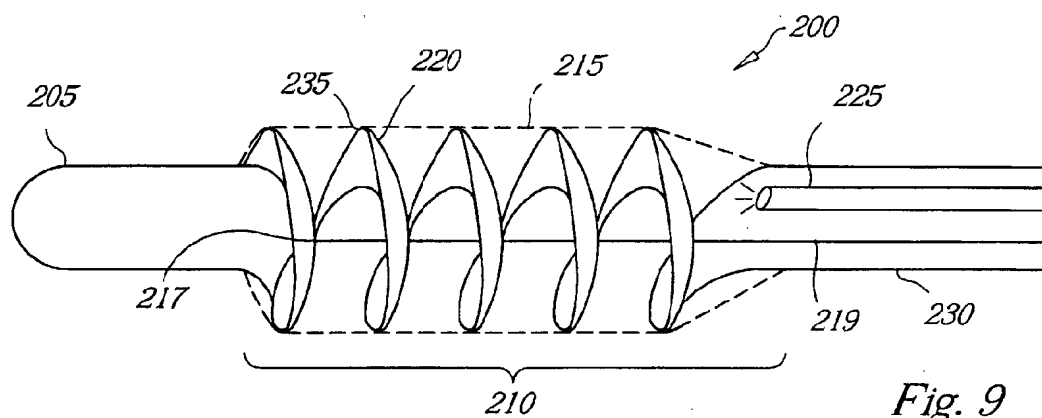


Fig. 8

3/6



4/6

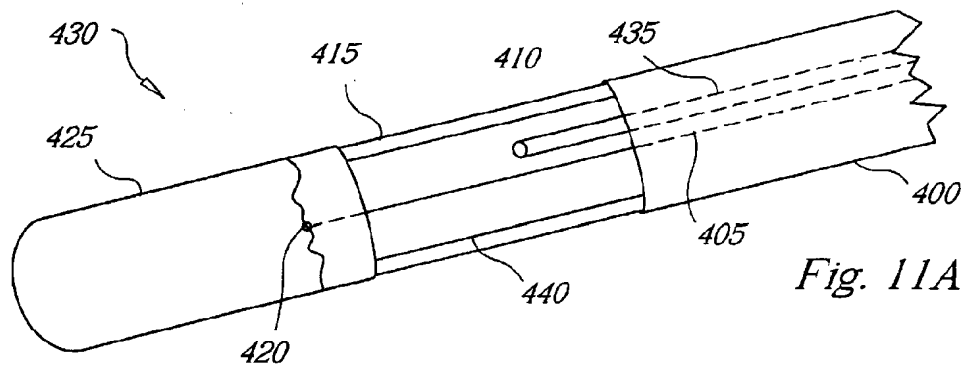


Fig. 11A

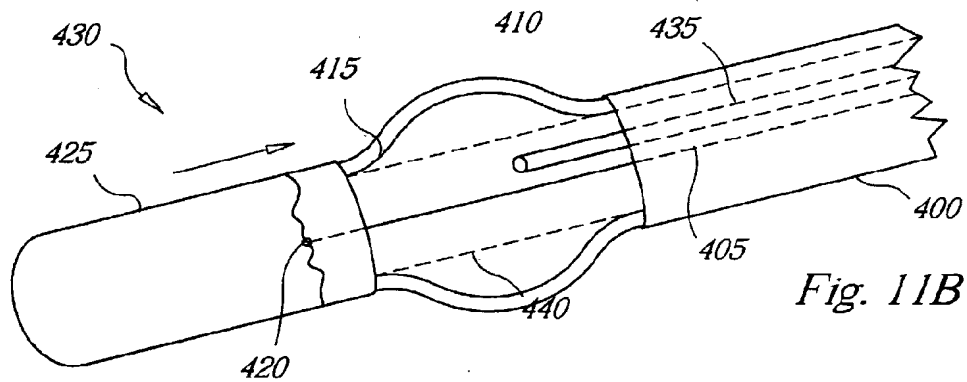


Fig. 11B

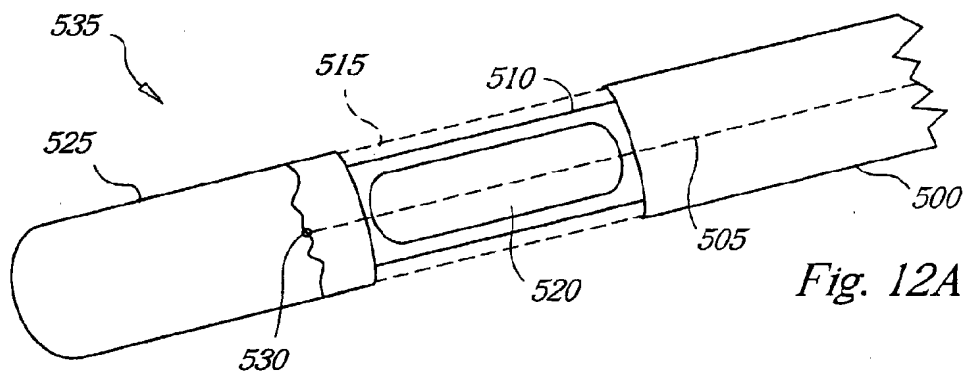


Fig. 12A

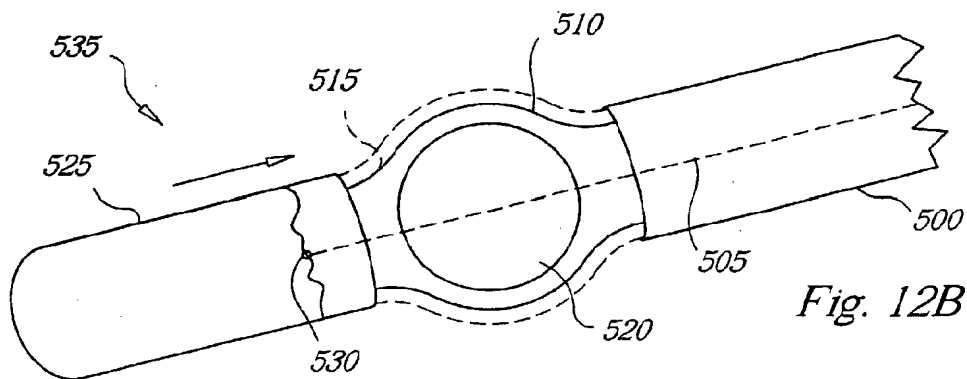
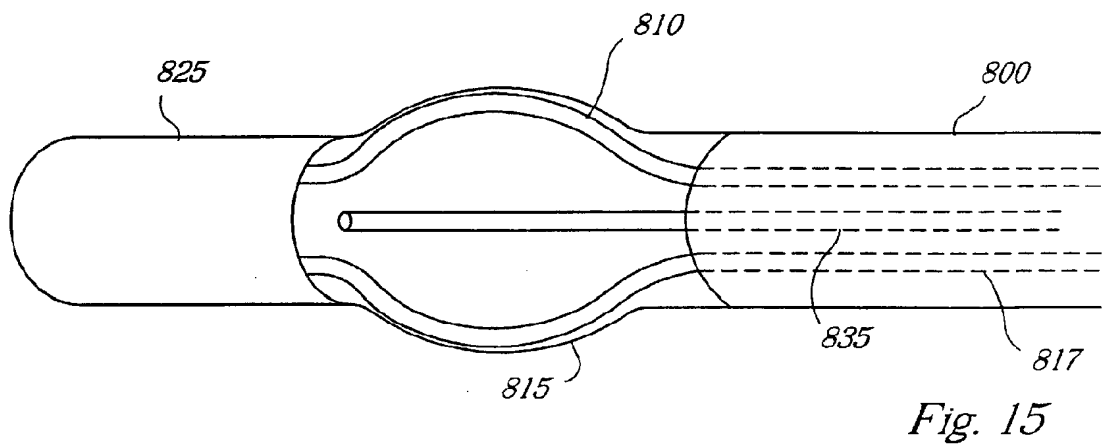
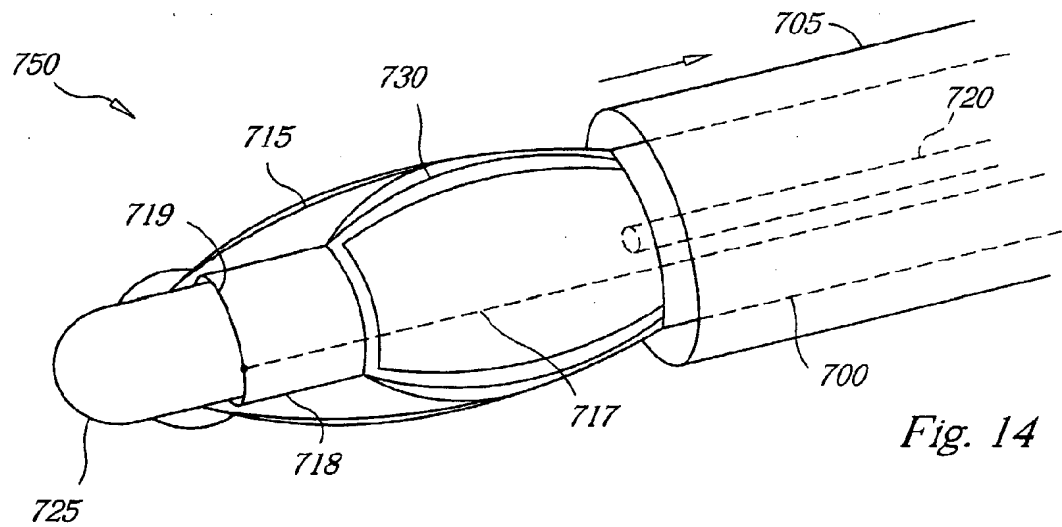
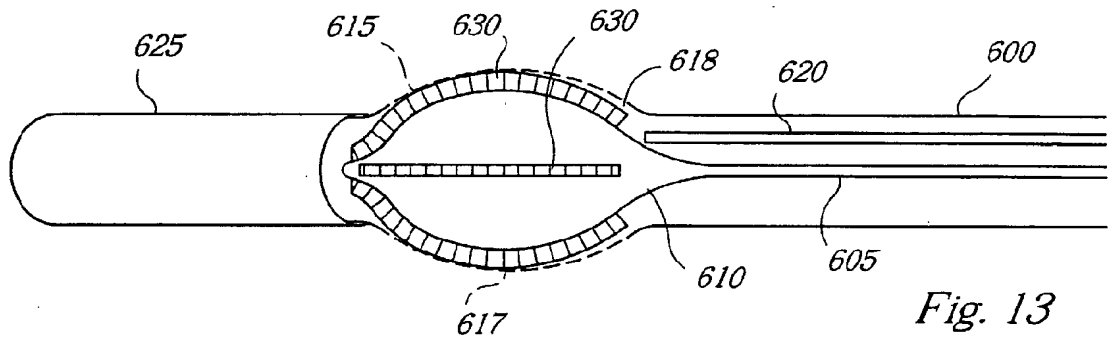


Fig. 12B

5/6



6/6

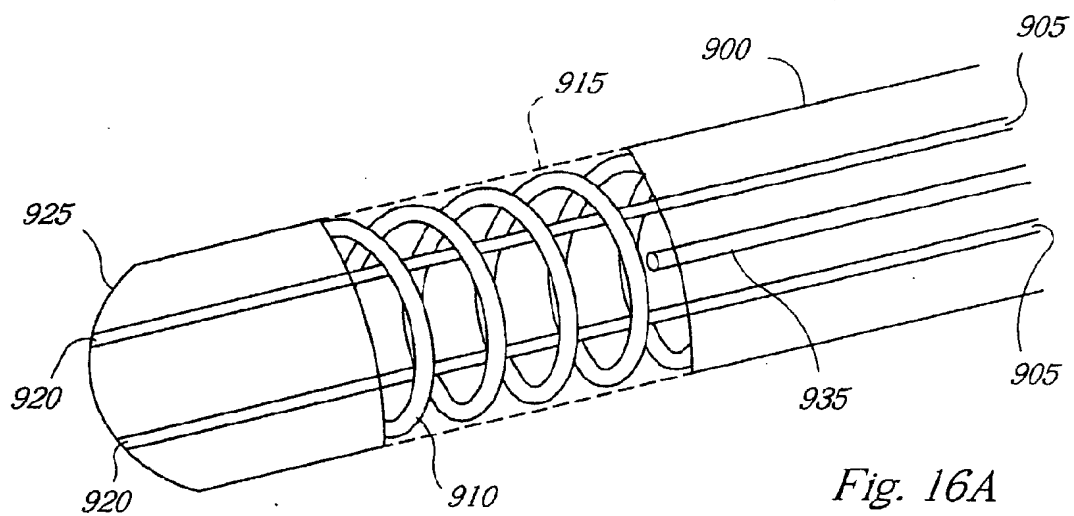


Fig. 16A

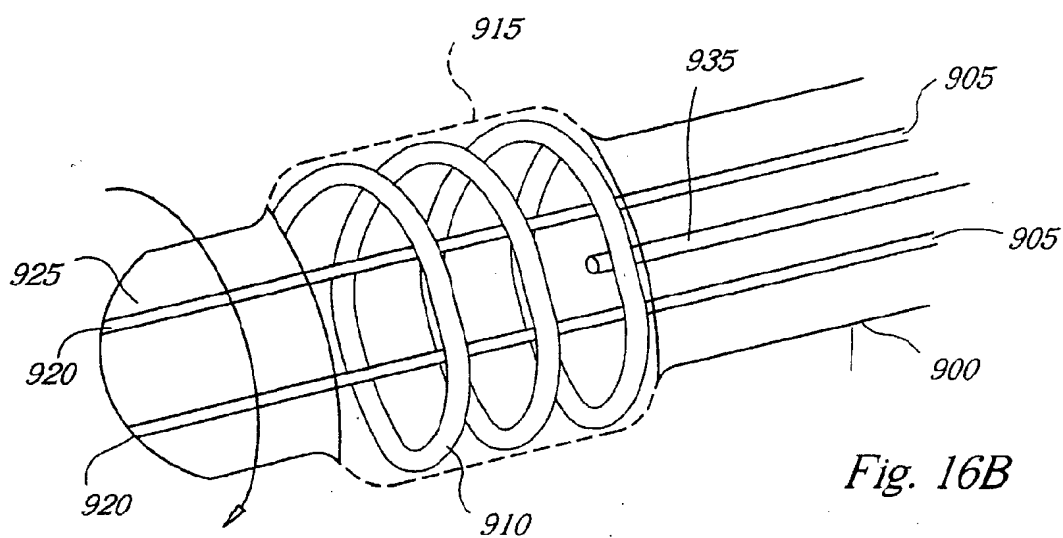


Fig. 16B

INTERNATIONAL SEARCH REPORT

Inter. Application No

PCT/US 01/02427

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61M25/10 A61B18/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 98 38934 A (SCIMED LIFE SYSTEMS INC) 11 September 1998 (1998-09-11) abstract page 6, paragraph 1; figure 1 page 8, paragraph 2 -page 10, paragraph 1; figure 3 page 12, last paragraph -page 14, paragraph 1 ---	1
A	WO 91 05528 A (GRANULAB B V) 2 May 1991 (1991-05-02) abstract ---	1
A	US 5 772 681 A (LEONI GIANNI) 30 June 1998 (1998-06-30) abstract ---	1
	--- -/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

& document member of the same patent family

Date of the actual completion of the international search

28 June 2001

Date of mailing of the international search report

05/07/2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Nielsen, M

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 01/02427

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,A	WO 00 54684 A (ODYSSEY TECH INC) 21 September 2000 (2000-09-21) abstract; figure 1 ---	1
P,A	WO 00 47118 A (JAYARAMAN SWAMINATHAN) 17 August 2000 (2000-08-17) abstract page 5, line 31 -page 6, line 7; figures 6,7 -----	1

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 01/02427

INTERNATIONAL SEARCH REPORT					
Patent document cited in search report		Publication date	Patent family member(s)		Publication date
WO 9838934	A	11-09-1998	US	5868735 A	09-02-1999
			EP	0910295 A	28-04-1999
WO 9105528	A	02-05-1991	NONE		
US 5772681	A	30-06-1998	DK	23293 A	03-09-1994
			AT	193657 T	15-06-2000
			AU	6202394 A	26-09-1994
			DE	69424862 D	13-07-2000
			DE	69424862 T	04-01-2001
			WO	9420166 A	15-09-1994
			EP	0687189 A	20-12-1995
WO 0054684	A	21-09-2000	AU	3884200 A	04-10-2000
WO 0047118	A	17-08-2000	AU	2679799 A	29-08-2000